K102566

JUN - 3 2011

510(k) SUMMARY

SUBMITTER INFORMATION

Company Name:	Diros Technology Inc.
Company Address:	232 Hood Road Markham, ON L3R 3K8
Company Phone:	(905) 415-3440
Company Fax:	(905) 415-0667
Contact Person:	George Darmos, President

DEVICE IDENTIFICATION

Trade/Proprietary Name:	Diros OWL Cannulae.
Classification:	II
Generic Device Name:	Cannulae
Classification Name:	Probe, Radiofrequency Lesion
Product Code:	GXI
Regulation Number:	21 CFR 882.4725

Devices to Which Substantial Equivalence is Claimed:

Top Neuropole Needles (ST, X, RC, XE and TL):	K062946
Top Neuropole Needles:	K080771
Diros OWL Cannulae:	K010202
Neurotherm Radio Frequency Cannulae:	K994344
Cosman Cannulae:	K060799
Epimed RF Cannula:	K041021
Baylis BMC RF Cannula	K972846

DEVICE DESCRIPTION

The Diros OWL Sterile Single Use Disposable Cannulae models 466, 467, DXE, DRC, DST, DHC are single use disposable cannulae designed for use with the Diros OWL RF Lesion Generator, model URF-3AP. The models DRC, DXE, DHC and DST provide flexible injection ports and are used to administer for the delivery of local anaesthesia. The DXE and DHC models along with the standard RF cannulae product line additionally provide the capability for delivery of RF therapy. The DHC model includes an embedded thermocouple for thermally controlled lesion generation. The Diros OWL Sterile Single Use Disposable Cannulae are available in multiple sizes. The cannulae gauge ranges from 18 to 24 and the length from 30mm to 200mm. All cannulae in this submission are for single use only and are supplied sterile.

K102566

INTENDED USE

The Diros OWL cannulae are injection needles which may be used either for percutaneous nerve blocks with local anesthetic solution or for radiofrequency lesioning. A nerve is localized either by using electrostimulation through the needle or by injecting contrast medium through the needle and using radiography concomitantly. The nerve may then be blocked by injecting local anesthetic solution or a radiofrequency lesion may be made.

SUBSTANTIAL EQUIVALENCE

The Diros OWL Sterile Single Use Disposable Cannulae models 466, 467, DXE, DRC, DST and DHC have the same intended use, technological characteristics, material properties, and dimensions as the identified legally marketed predicate devices.

CONCLUSIONS

The intended use and performance characteristics of the Diros OWL Cannulae is the same as the predicates and raise no new questions of safety and effectiveness.

The Diros OWL Cannulae are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Diros Technologies
% Mr. George Darmos
President
232 Hood Road
Markham, Ontario
Canada, L3R 3K8

JUN - 3 2011

Re: K102566
Trade/Device Name: Diros OWL Cannulae
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency Lesion Probe
Regulatory Class: Class II
Product Code: GXI
Dated: May 10, 2011
Received: May 12, 2011

Dear Mr. Darmos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K102566

Device Name: Diros OWL Single Use Disposable Cannula (466, 467, DXE, DRC, DST, DHC)

Indications for Use:

The Diros OWL cannulae are injection needles which may be used either for percutaneous nerve blocks with local anesthetic solution or for radiofrequency lesioning. A nerve is localized either by using electrostimulation through the needle or by injecting contrast medium through the needle and using radiography concomitantly. The nerve may then be blocked by injecting local anesthetic solution or a radiofrequency lesion may be made.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K102566